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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,705	02/06/2001	Karl Guegler	CLO01010	5353

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EXAMINER	
BUNNER, BRIDGET E	

ART UNIT	PAPER NUMBER
1647	3

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/776,705	GUEGLER ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,8,9,13 and 24-28* is/are pending in the application.

4a) Of the above claim(s) *13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,8,9 and 24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *4,8,9,13 and 24-28* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 July 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election of Group III, claims 4-5, 8-11, and 22-23, drawn to an isolated nucleic acid molecule, vector, host cell, and method of recombinant protein expression in Paper No. 12 (11 November 2002) is acknowledged. The traversal is on the ground(s) that the Examiner reconsider the claim division and include claim 13 (Group VII) in the elected group. Applicant argues that the point of novelty of claim 13 is the nucleic acid molecules of the claim from which it depends (claim 5). Applicant asserts that claim 13 provides a specific use (method of detecting a nucleic acid) of the subject matter and that examination of this claim would not unduly burden the Examiner with additional review issues. This is not found persuasive because the isolated nucleic acid molecule of Group III can be used in materially different processes other than the method of Group VII, such as in DNA purification or gene therapy. The inventions are distinct if the product claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Furthermore, the nucleic acid molecule of Group III and the method of detection of Group VII are unique inventions, requiring a unique search of the prior art. Searching all of the inventions in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

The requirement is still deemed proper and is therefore made FINAL.

Claim 13 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12 (11 November 2002).

Status of Application, Amendments and/or Claims

The amendment of 11 November 2002 (Paper No. 12) has been entered in full. Claims 1-3, 5-7, and 10-12, and 14-23 are cancelled, claims 4, 8, and 13 are amended, and claims 24-28 are added.

Claims 4, 8-9, and 24-28 are under consideration in the instant application.

Sequence Compliance

The Applicant's response to the Notice to Comply with Sequence Listing Requirements under 37 CFR §1.821 (Paper No. 8, 25 July 2002) has been considered and is found persuasive. Therefore, the requirements set forth in the Notice to Comply (Paper No. 7, 25 June 2002) are withdrawn. It is noted to Applicant that the STIC Systems Branch of the USPTO has deleted non-ASCII "garbage" at the end of the computer readable files.

New Sequence Compliance Rejection

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). **Specifically, the sequences disclosed in Figures 2C and 2D (other than SEQ ID NOs: 4 and 5) are not accompanied by the required reference to the relevant sequence identifiers.** This application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825). Please note that this objection may be overcome by the submission of new drawings or by amending the Brief Description of Drawings.

Specification

2. The disclosure is objected to because of the following informalities:

2a. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (pg 2, line 5; pg 5, lines 4-5; pg 21, lines 19 and 24). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

2b. The Brief Description of Drawings fails to refer to Figures 1A-1B, 2A-2E, and 3A-3AA.

2c. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "NUCLEIC ACID MOLECULES ENCODING HUMAN TRANSPORTER PROTEINS".

Appropriate correction is required.

Claim Rejections - 35 USC § 101 and § 112, first paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 4, 8-9, and 24-28 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation.

Specifically, claims 4, 8-9, and 24-28 are directed to an isolated nucleic acid molecule consisting of a nucleotide sequence consisting of (a) a nucleotide that encodes a protein comprising the amino acid sequence of SEQ ID NO: 2, (b) a nucleic acid molecule consisting of the nucleic acid sequence of SEQ ID NO: 1, (c) a nucleic acid molecule consisting of the nucleic acid sequence of SEQ ID NO: 3, and (d) a nucleic acid molecule that is completely complementary to a nucleic acid molecule of (a)-(c). The claims also recite a vector, host cell, and a process for producing a polypeptide.

The specification asserts that the transporter polynucleotides (SEQ ID NO:1 or 3) and polypeptide (SEQ ID NO: 2) of the present invention are related to the amino acid transport system A (ATA) family and are involved in sodium-dependent transport of short-chain aliphatic neutral amino acids that is repressible by alpha-(methylamino)isobutyric acid (pg 13, lines 22-27; pg 14, lines 1-25). However, the instant specification does not teach any significance or functional characteristics of the transporter polynucleotides (SEQ ID NO: 1 or 3) or polypeptide (SEQ ID NO: 2). The specification also does not disclose any methods or working examples that indicate the polynucleotides and polypeptide of the instant invention are involved in any of the abovementioned activities. Since significant further research would be required of the skilled artisan to determine how the claimed polypeptide is involved with the above-mentioned activities, the asserted utilities are not substantial. Additionally, transporter proteins are extremely diverse, as evidenced by Palacin et al. (Physiol Rev 78: 969-1054, 1998), and each new transporter molecule needs to be evaluated empirically to determine the precise role(s) it plays. Since the utility is not presented in mature form and significant further research is

required, the utility is not substantial. The specification asserts the following as patentable utilities for the claimed putative polynucleotides (SEQ ID NO: 1 or 3):

1) to produce a chimeric, fusion, or variant protein (pg 19, lines 16-31; pg 20, lines 1-10)

2) as hybridization probes for cDNA and genomic DNA (pg 42, lines 10-21; pg 43, lines 19-29; pg 44, lines 13-18, 29-31; pg 45, lines 1-22)

3) as primers for a nucleic acid amplification (pg 42, lines 18-21; pg 43, lines 19-20; pg 44, lines 1-3)

4) to design ribozymes corresponding to mRNA produced (pg 44, lines 21-22)

5) to construct a transgenic animal (pg 44, lines 27-28; pg 60-62)

6) in tissue typing (pg 44, lines 29-31, pg 45, lines 1-22)

7) to screen drugs to identify compounds that modulate transporter nucleic acid expression (pg 45, lines 23-31; pg 46; pg 47, lines 20)

8) in diagnostic assays to measure the qualitative changes or mutations in transporter nucleic acid expression (pg 47, lines 21-31; pg 48-49)

9) for gene therapy (pg 50)

10) for an array or microarray (pg 51, lines 9-30; pg 52-53)

Each of these shall be addressed in turn.

1) to produce a chimeric, fusion, or variant protein to produce a variant polypeptide.

This asserted utility is not substantial or specific. Such assays can be performed with any polynucleotide. Further, the specification discloses nothing specific or substantial for the chimeric, fusion, or variant polypeptide that is produced by this method. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

2) as hybridization probes for cDNA and genomic DNA. This asserted utility is not substantial or specific. Hybridization probes can be designed from any polynucleotide sequence. Further, the specification does not disclose specific cDNA, DNA, or RNA targets. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

3) as primers for a nucleic acid amplification. This asserted utility is not substantial or specific. Primers can be designed from any polynucleotide sequence. Further, the specification does not disclose a specific DNA target. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

4) to design ribozymes corresponding to mRNA produced. This asserted utility is not specific or substantial. Ribozymes can be designed from any DNA/RNA sequence. Additionally, the specification does not disclose a specific DNA/RNA target. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

5) to construct a transgenic animal. This asserted utility is not specific or substantial. The specification does not disclose diseases associated with a mutated, deleted, or translocated transporter gene (SEQ ID NOs: 1 or 3). Significant further experimentation would be required of the skilled artisan to identify such a disease. The specification discloses nothing about whether the gene will be "knocked in" or "knocked out" or what specific tissues and cells are being targeted. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

6) in tissue typing. This asserted utility is not substantial or specific. Such assays can be performed with any polynucleotide. Further, the specification does not disclose specific DNA sequences for use as markers for RFLP, to prepare primers, or to amplify DNA. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

7) to screen drugs to identify compounds that modulate GPCR nucleic acid expression. This asserted utility is not specific or substantial. The specification discloses nothing specific or substantial for the compounds that can be identified by this method. The specification also discloses nothing about the normal levels of expression of the polynucleotide or a specific DNA target. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

8) in diagnostic assays to measure the qualitative changes or mutations in the nucleic acid molecule. This asserted utility is not specific or substantial. The specification does not disclose disorders associated with a mutated nucleic acid molecule consisting of the nucleic acids of SEQ ID NO: 1 or 3. Significant further experimentation would be required of the skilled artisan to identify individuals with such a disease. The specification also discloses nothing about the normal levels of expression of the polynucleotide or a specific DNA target. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

9) for gene therapy. This asserted utility is not specific or substantial. The specification does not disclose diseases associated with a mutated, deleted, or translocated transporter gene of SEQ ID NO: 1 or 3. Significant further experimentation would be required of the skilled artisan

to identify individuals with such a disease. Since this asserted utility is also not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

10) for an array or microarray. This utility is not specific or substantial. Such arrays can be designed from any polynucleotide sequence. Further, the specification does not disclose specific cDNA, DNA, or RNA target sequences. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

4. Claims 4, 8-9 and 24-28 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 24 is rejected as being indefinite because the claims recite a recombinant method for producing a polypeptide comprising insertion of the polynucleotide of claim 4 into a host cell. Claim 4(d) recites a polynucleotide consisting of "a nucleotide sequence that is completely

complementary to a nucleotide sequence of (a)-(c)". It is not clear how the polynucleotide complements of claim 4(d) produce the polypeptide disclosed in the instant application. A complement is a sequence of nucleotide bases in one strand of a DNA or RNA molecule that is exactly complementary (adenine-thymine, adenine-uracil, or guanine-cytosine) to that on another single strand.

7. Claim 25 is rejected as being indefinite because it cannot be determined what SEQ ID NO the claim is directed to. For example, claim 25 recites "a nucleotide sequence set forth in SEQ ID NO: 2". However, in the specification, SEQ ID NO: 2 is an amino acid sequence and not a nucleic acid sequence. (Please note that this issue could be overcome by amending the claim to recite "a nucleotide sequence set forth in SEQ ID NO: 1" or "a nucleotide sequence encoding the polypeptide set forth in SEQ ID NO: 2".)

8. Claim 27 recites the limitation "the protein of SEQ ID NO: 4" in line 3. There is insufficient antecedent basis for this limitation in the claim. (It is noted to Applicant that this issue could be overcome by amending the claim to recite "the protein of SEQ ID NO: 2".)

9. Claim 28 recites the limitation "A vector according to claim 28" in line 1. There is insufficient antecedent basis for this limitation in the claim because claim 28 is referring to itself. (It is noted to Applicant that this issue could be overcome by amending the claim to recite "A vector according to claim 27".)

Conclusion

No claims are allowable.

The art made of record and not relied upon is considered pertinent to applicant's disclosure:

Montgomery et al. Accession No. AC005854

Muzny et al. Accession No. AC008014

Hatanaka et al. Biochim Biophys Acta 1510(1-2): 10-17, 2001

Hatanaka et al. FEBS Lett. 505(2):317-320, 2001.

Hatanaka et al. Biochim Biophys Acta. 1467(1):1-6, 2000.

Wang H et al. Biochem Biophys Res Comm 273(3): 1175-1179, 2000.

Sugawara et al. Biochim Biophys Acta. 1509(1-2):7-13, 2000.

Sugawara et al. J Biol Chem 275(22): 16473-16477, 2000

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C Kemmerer

BEB
Art Unit 1647
January 27, 2003